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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/285,429	04/02/1999	BRET A. SHIRLEY	5784-9	3707

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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 04/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/285,429

Applicant(s)

SHIRLEY ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 21-34, 45 and 46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-34 and 45-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

1. The finality of the previous Office Action dated October 14, 2003 is withdrawn because of a new ground of rejection.

#### ***Status of the Claims***

2. Claims 21-34 and 45-46 are pending.

Applicants' amendment filed March 17, 2004 is acknowledged, and applicant's response has been fully considered. Claim 1-20, 35-44 and 47-52 have been cancelled. Therefore, claims 21-34 and 45-46 are examined.

#### **Rejection Withdrawn**

##### ***Claim Rejections-Obviousness Type Double Patenting***

3. The previous rejection of claims 1-8, 13, 14, 38-40 and 47-50 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6, 9, 12, 13, 36-40, 45, 47, 48 of copending application US 2002/0172661 A1 (10/035,397), is withdrawn in view of applicants' cancellation of the claim in the amendment filed March 17, 2004.

##### ***Claim Rejections - 35 USC § 112***

4. The previous rejection of claims 1-10, 13, 14 and 38-40, under 35 U.S.C. § 112, second paragraph, is withdrawn in view of applicants' cancellation of the claim in the amendment filed March 17, 2004.

##### ***Claim Rejections - 35 USC § 102***

5. The previous rejection of claims 1-5, 9, 10, 13, 14, 38-40, 47-49, 51 and 52 under 35 USC § 102(e), as being anticipated by Van't Veer et al. (U. S. Patent 5,977,057, May 8, 1996), is

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withdrawn in view of applicants' cancellation of the claim in the amendment filed March 17, 2004.

6. The previous rejection of claims 1-5, 9, 10, 13 and 38-40 under 35 USC § 102(e), as being anticipated by Cleland et al. (US 2002/0004481 A1, filed June 11, 1998), is withdrawn in view of applicants' cancellation of the claim in the amendment filed March 17, 2004.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 21-34 and 45-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Clark *et al.* (U. S. Patent 5,597,802, published January 28, 1997).

Clark *et al.* teach a composition comprising IGF-I, an osmolyte, a stabilizer and a buffer solution of about pH 5-5.5, and a formulation comprising mixing the IGF-I composition with a buffered solution comprising GH at pH 6.0, which can be administered parenterally, preferably by injection, and the formulation is sterile (column 5, lines 44-52; column 9, line 57-column 10, line 10; column 13. lines 38-41), wherein IGF-I can be a recombinant human IGF-I (column 8, lines 46-50), and the carrier can be a succinate buffer having a concentration of about 5 to 100 mM and a pH of about 5 to 6 for GH+IGF-I formulation, and containing about 2-50 mg/ml of osmolyte (also referred as isotonic modifier) such as sodium chloride (corresponding to 34-855

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mM; column 12, lines 14-35, column 13, lines 16-24; claims 21-32, 45 and 46). The reference also teaches the final preparation can be a stable liquid or lyophilized solid (column 13, lines 33-37; claims 33 and 34).

8. Claims 21-34 and 45-46 are rejected under 35 U.S.C. 102(e) as being anticipated by Clark *et al.* (U. S. Patent 5,783,556, filed August 13, 1996).

Clark *et al.* teach a parental composition comprising IGF-I and NPH insulin in a pharmaceutically acceptable carrier (column 5, lines 55-67), wherein IGF-I can be a recombinant human IGF-I (column 8, lines 7-11), and the carrier can be a succinate buffer having a concentration of about 5 to 100 mM and a pH of about 5 to 7, and containing about 0.05 to 0.3 M osmolyte (also referred as isotonic modifier) such as sodium chloride (column 12, lines 13-37, column 13, lines 18-29; claims 21-32). The reference also teaches the composition of IGF-I and NPH insulin is sterile (column 13, lines 44-51) and is preferably administered by injection (column 9, lines 62-63; claims 45 and 46); and the final preparation can be a stable liquid or lyophilized solid (column 12, lines 11-12; claims 33 and 34).

### ***Conclusion***

9. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*  
Patent Examiner

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April 12, 2004

*Christopher S. F. Low*  
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